
HOUSE BILL 3385

State of Washington 60th Legislature 2008 Regular Session

By Representatives Chase, O'Brien, Skinner, and Hankins

Read first time 03/05/08. Referred to Committee on Health Care & Wellness.

1 AN ACT Relating to biological research laboratory health and
2 safety; adding a new chapter to Title 70 RCW; and prescribing
3 penalties.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5 **WASHINGTON STATE BIOLOGICAL LABORATORY RULES**

6 **PREAMBLE**

7 NEW SECTION. **Sec. 1.** Biotechnology research promises advances in
8 fields ranging from medicine and agriculture to combating bioterrorism.
9 It is a well-funded and rapidly growing enterprise in research centers
10 around the United States, including Seattle.

11 As with other technologies such as nuclear energy, research in
12 biotechnology also carries risks. Some materials used in biotechnology
13 labs are dangerous and/or environmentally destructive. Improper
14 handling of those materials could cause loss of life, personal injury,
15 environmental destruction, and property damage.

16 Although research in biotechnology is relatively new, exposures to
17 dangerous substances from various biotechnology labs around the
18 country, including exposures at a biotechnology lab operated in

1 downtown Seattle, already have occurred. Nonetheless, biotechnology
2 research in Seattle is largely unregulated. Indeed, human exposures
3 have occurred without the public ever being informed.

4 Safe and responsible biotechnology research requires that the
5 research be transparent, subject to independent oversight and
6 regulation, and that violations of those regulations be effectively
7 sanctioned. These regulations are established in order to accomplish
8 those ends.

9 **PART I**

10 **BIOLOGICAL RESEARCH LABORATORY HEALTH AND SAFETY PROGRAM**
11 **FOR WASHINGTON STATE**

12 NEW SECTION. **Sec. 2.** The definitions in this section apply
13 throughout this chapter unless the context clearly requires otherwise.

14 (1) "Biological agent" means any naturally occurring,
15 bioengineered, or genetically altered or synthesized microorganism
16 including, but not limited to, bacteria, virus, fungus, and protozoa,
17 or infectious substance or vector, or component of any such
18 microorganism or infectious substance capable of causing death,
19 disease, or other physiological change in a human, an animal, a plant,
20 or other living organism; deterioration of food, water, equipment,
21 supplies, or material of any kind; or having a deleterious effect on
22 the environment.

23 (2) "Biosafety level 2 laboratory" means a laboratory that is
24 designed, equipped, or operated as a biosafety level 2 laboratory as
25 defined by the United States national institutes of health guidelines
26 for research involving recombinant DNA molecules.

27 (3) "Biosafety level 3 laboratory" means a laboratory that is
28 designed, equipped, or operated as a biosafety level 3 laboratory as
29 defined by the United States national institutes of health guidelines
30 for research involving recombinant DNA molecules.

31 (4) "Biosafety level 4 laboratory" means a laboratory that is
32 designed, equipped, or operated as a biosafety level 4 laboratory as
33 defined by the United States national institutes of health guidelines
34 for research involving recombinant DNA molecules.

35 (5) "Commission" means the Washington state biosafety commission
36 created in section 5 of this act.

1 (6) "Department" means the department of health.

2 (7) "Facility" means a building or combination of buildings under
3 common control and ownership containing one or more laboratories
4 subject to a common institutional biosafety committee.

5 (8) "Laboratory" means a room or rooms used primarily for
6 biological research, development, nonroutine testing, or
7 experimentation activity, or any room or rooms where vertebrate animals
8 are contained under animal biosafety levels described in national
9 institutes of health guidelines including, but not limited to, all
10 enclosed areas with a laboratory containment area, including any rooms,
11 closets, facilities, freezers, refrigerators, or incubators where
12 biological agents are stored, fermented, grown, proliferated, or
13 colonized.

14 (9) "Principal investigator" means the individual designated by a
15 research sponsor to direct the biological research project or program
16 the research sponsor conducts at biosafety laboratory levels 2 or 3,
17 who is responsible to the research sponsor for the scientific and
18 technical direction of that project or program.

19 (10) "Research sponsor" means any state, public or private
20 corporation or authority, individual, trust, firm, joint stock company,
21 limited liability company, partnership, research group, task force,
22 university program, association, or entity or group thereof, group of
23 persons, and agency or political subdivision of the state of
24 Washington, the federal government, or other government, subdivision,
25 agent or agency thereof, which operates or which proposes to operate a
26 biosafety level 2 and/or biosafety level 3 laboratory in Washington
27 state.

28 (11) "Toxin" means any toxic material or product of plants,
29 animals, microorganisms including, but not limited to, bacteria, virus,
30 fungus, rickettsia, or protozoa, misfolded protein, infectious
31 substance, or a recombinant or synthesized molecule, whatever its
32 origin or method of production. "Toxin" includes any poisonous
33 substance or biological product that may be engineered as a result of
34 biotechnology produced by a living organism; or any poisonous isomer or
35 biological product, homolog, or derivative of such substance.

36 NEW SECTION. **Sec. 3.** There is established in the department, a

1 high containment biological research laboratory health and safety
2 program for biosafety level 2 and 3 laboratories located in Washington
3 state.

4 (1) The program shall provide standards for location, operation,
5 and maintenance of high containment biological research laboratories
6 and the oversight of such laboratories to protect the safety of
7 laboratory workers, the public, and the environment from regulated
8 agents and toxins.

9 (2) The program shall provide standards for the transportation,
10 relocation, shipment, delivery, conveyance, and receipt of regulated
11 agents and toxins.

12 (3) The program shall provide for procedures which would allow the
13 department to order biosafety level 2 and 3 laboratories to immediately
14 cease and desist work on a project and lock down and/or refrain from
15 any activity that the department determines could cause immediate and
16 irreparable injury, loss, or damage.

17 (4) The program shall be administered by the commission.

18 NEW SECTION. **Sec. 4.** The department shall adopt rules for the
19 implementation of the program that establish the criteria for
20 determining appropriate locations for siting a building or facility
21 that contains a laboratory, including whether a laboratory may be
22 created within an existing building. The criteria shall include, at a
23 minimum, that:

24 (1) Sites shall not be within a floodplain, within eight hundred
25 yards of property whose regular use could endanger the site due to fire
26 or explosion; or near an area of traffic congestion that might impede
27 emergency access for evacuation or endanger motorists or pedestrians.

28 (2) Sites shall have sufficient land available to provide for a
29 reasonable buffer around the buildings which shall be no less than one
30 hundred fifty unobstructed feet in each direction.

31 (3) Other criteria for consideration shall include proximity of
32 wetlands, waterways, and water bodies; the relationship of the site to
33 groundwater elevation; the nature and extent of residential areas and
34 schools in proximity to the site; the availability and suitability of
35 access roads to the site, including the ability of first responders to
36 access the site in an emergency; the potential for adverse public

1 health and safety impacts; potential impact of increased traffic volume
2 on adjacent roads; and the potential threat of terrorist attack or
3 infiltration of the building.

4 (4) The department shall set forth procedures, consistent with this
5 section, for the submission, review, and approval of permit and
6 construction applications, and the issuance and renewal of permit and
7 construction applications. Permits may be issued which contain
8 conditions or restrictions that serve and protect public health and
9 safety.

10 (a) The application for a permit or renewal of a permit shall be
11 acted upon within sixty days of submission of a completed application.
12 The department is not obligated to review incomplete applications. If,
13 at the conclusion of the sixty-day period, the review of the
14 application is not complete, the department may issue to a research
15 sponsor a provisional permit if the application is complete and it
16 establishes substantial compliance with this chapter. A provisional
17 permit shall not exceed one hundred twenty days in duration, and shall
18 not be renewed or extended.

19 (b) To the extent that the permit application may require the
20 submission or review of trade secret information under RCW 19.108.010,
21 the research sponsor may submit such information under seal.
22 Commission members and their staff shall be prohibited from disclosing
23 trade secret information submitted under seal pursuant to this
24 subsection to any third party, and such matter shall be used by the
25 commission and its staff for no purpose other than the permitting
26 process. Reckless or intentional disclosure of trade secret
27 information submitted under seal is a misdemeanor.

28 (c) The denial of a permit application may be appealed pursuant to
29 the rules of practice and procedure of the King county board of
30 appeals.

31 (d) Prior to issuance of any permit for a biosafety level 3
32 laboratory under this chapter, the department must hold, with sixty
33 days, notice to the public of the application and its contents, a
34 public hearing on the application with opportunity for reasonable
35 public comment on whether the application should be granted.

36 **PART II**

1 two community representatives who have no financial, professional,
2 familial, close social, or business relationship in or with the
3 regulated research sponsor, its affiliates or subsidiaries, employees,
4 contractors, subcontractors, or investors. Community representatives
5 shall be selected by joint approval of the department and neighborhood
6 organizations representing the communities or community where the
7 laboratory is located. Community representatives shall be individuals
8 whose principal residence is within three miles of the laboratory, and
9 whose principal residence has been within three miles of the laboratory
10 for at least two years immediately preceding their selection as such.

11 (2) Each committee shall report to the commission. The committee
12 will meet at least four times a year and at such other times as may be
13 specified by the commission, or guidelines issued under this chapter,
14 or as requested by any member of the committee. Except for executive
15 sessions, meetings of the committee and all of its subcommittees shall
16 be open to the public. Notice of such public meetings and the conduct
17 of public meetings shall be in accordance with the Washington state
18 open public meetings act.

19 (3) Each committee shall file an annual report with the commission.
20 The report shall include, at a minimum, complete copies of all
21 committee minutes for the preceding reporting period, certification
22 that the laboratory and/or facility is in compliance with this chapter,
23 a report on any quality assurance and quality improvement efforts made
24 during the period, a complete roster of current committee members, and
25 an update of any information relative to the permit application. To
26 the extent committee minutes contain information that jeopardizes trade
27 secret information as defined by RCW 19.108.010, the commission shall
28 develop procedures for assuring confidentiality of said information.
29 Committee minutes shall, at a minimum, conform to the national
30 institutes of health office of biotechnology activities issued guidance
31 concerning the preparation of, and public access to, minutes of
32 committee meetings and department of health and human services guidance
33 on the content of minutes of committee meetings, dated February 23,
34 2007.

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PART IV
PERMIT FEES

1 (f) Procedures and policies relating to laboratory safety
2 including, but not limited to, research, training, security, laboratory
3 inspections, transportation, waste disposal, commissioning,
4 decommissioning, decontamination, termination of work with biological
5 agents and toxins, training of all employees, visitors, or students,
6 and first responder plans including evacuation and emergency response;

7 (g) Other information as required by the commission and guidelines
8 issued under this chapter; and

9 (h) Any incident in which the research sponsor, any of its
10 officers, employees, or any other person who will work in the lab or
11 exercise authority over activity in the lab was found to have violated,
12 or was sanctioned for violating, any law, rule, or ordinance regulating
13 the environment, health, safety, public disclosure, and/or the
14 truthfulness of statements.

15 **PART VI**

16 **EMERGENCY SUSPENSION OF PERMIT**

17 NEW SECTION. **Sec. 9.** If the secretary of the department becomes
18 aware of credible evidence that activity at a facility licensed for, or
19 seeking a license for, operation under this chapter is likely to pose
20 a significant and imminent threat to human health or to the environment
21 or to cause substantial property damage, the secretary may find that
22 immediate closure of the facility is required to avert such danger and
23 order all research and related activity at that facility suspended
24 until such time as the secretary finds that threat to have been
25 resolved. If the research sponsor believes the secretary's finding to
26 have been unwarranted, it may seek reversal of the decision in a county
27 superior court based on clear and convincing evidence.

28 **PART VII**

29 **REPORTING REQUIREMENTS**

30 NEW SECTION. **Sec. 10.** (1) The licensed research sponsor must,
31 within twenty-four hours, report to the commission any incident in
32 which there was human exposure to a biological agent or toxin, and/or
33 a reasonable likelihood of such exposure, including all incidents
34 resulting in actual or recommended prophylactic quarantine or drug use.

1 (2) A research sponsor shall report any release or spread of a
2 biological agent or toxin, or the reasonable likelihood of a release or
3 spread, outside the primary containment area of a biosafety level
4 laboratory to the department as soon as possible and in no case more
5 than twenty-four hours after the event. The report shall also be
6 provided to the commission.

7 (3) The facility or laboratory shall also provide the institutional
8 biosafety committee with a detailed report of all incidents, accidents,
9 and other events that cause or are suspected to have caused a threat to
10 the public health, death, illness, or bodily injury to any person to
11 report said incident not later than seventy-two hours after the
12 incident. The report shall be a public record.

13 (4) On an annual basis, the facility or laboratory shall provide
14 the commission with third party certification for all biosafety
15 cabinets, autoclaves, tissue digesters, incubators, centrifuges, and
16 all other major laboratory equipment.

17 **PART VIII**

18 **TRAINING**

19 NEW SECTION. **Sec. 11.** Each facility with a laboratory shall have
20 and implement a plan to provide adequate training for the proper
21 handling of biological agents and toxins that might be present therein.
22 Such training shall include, but not be limited to, decontamination
23 methods, personnel safety precautions and work habits, early warning
24 disease surveillance, and accident response actions and notifications,
25 access control and monitoring, personnel management, inventory and
26 accountability, information security, and transport of biological
27 agents. Each facility shall provide a training plan to its
28 institutional biosafety committee and to the commission for approval
29 and shall update the plan annually, or as necessary. The training plan
30 shall ensure that all laboratory staff, facility workers, and
31 researchers, including the principal investigator for each facility,
32 are trained adequately. The principal investigator shall participate
33 in the creation and implementation of the training plan. No individual
34 other than a local, state, or federal government representative with
35 authorized access for regulatory compliance for investigative purposes

1 may enter the biosafety level laboratory located within a facility
2 without first completing the facility's training plan.

3 **PART IX**
4 **WASTE MANAGEMENT**

5 NEW SECTION. **Sec. 12.** Each facility regulated by this chapter
6 shall implement a waste management and decontamination plan submitted
7 to and approved in advance as a condition of permitting by the
8 commission.

9 **PART X**
10 **EMERGENCY RESPONSE PLAN**

11 NEW SECTION. **Sec. 13.** A facility regulated by this chapter shall
12 develop an emergency response plan, in conjunction with local and state
13 officials, that addresses security threats and releases involving the
14 spread of biological agents and toxins. The emergency response plan
15 shall comply with local, state, and federal plans already in existence.
16 The plan must address such events as severe weather, earthquakes, power
17 outages, power line breaks, terrorism, and other natural, accidental,
18 or intentional disasters or emergencies. The emergency response plan
19 shall, at a minimum, address the following:

- 20 (1) Particular hazards associated with specific biological agents
21 and toxins located at the facility or its laboratories;
- 22 (2) Personnel roles, lines of authority, training, and
23 communication;
- 24 (3) Emergency assessment and prevention;
- 25 (4) Site security and control;
- 26 (5) Evacuation routes and procedures;
- 27 (6) Decontamination;
- 28 (7) Emergency medical treatment and first aid;
- 29 (8) Emergency alerting and response procedures;
- 30 (9) Personal protective and emergency equipment;
- 31 (10) Regulatory scheduled preparedness exercises coordinated with
32 Seattle public health and safety officials;
- 33 (11) Critique of response and follow up subsequent to an incident;
- 34 and

1 (12) Communication to the public and the local news media.

2 **PART XI**
3 **INSPECTIONS**

4 NEW SECTION. **Sec. 14.** The commission has the authority to review
5 all documentation relating to the operations of the facility and any
6 laboratories therein, and to conduct a physical inspection of any
7 facility or laboratory, with or without prior notice, so long as such
8 inspection is conducted at a reasonable time under the circumstances
9 and in a manner that maintains the health and safety systems of the
10 laboratories involved. Failure to provide any requested documentation
11 or access to a laboratory for the purpose of inspection will result in
12 a fine and/or the immediate suspension or restriction of a research
13 sponsor's permit to operate. A failure to provide requested
14 documentation or access to a laboratory for the purpose of inspection
15 for a period exceeding seven days shall result in suspension of the
16 facility or laboratory permit to operate at least until such time as
17 the failure has been rectified.

18 **PART XII**
19 **PROHIBITIONS**

20 NEW SECTION. **Sec. 15.** (1) Any biosafety level 2 or 3 laboratory
21 research or project is forbidden in Washington state if it is
22 reasonably likely to:

23 (a) Be used to harm human health, human habitat, agriculture, or
24 the breeding or raising of livestock;

25 (b) Render an immunization ineffective or lessen immunity in
26 humans, animals, or plants;

27 (c) Confer to a biological agent or toxin resistance of clinically
28 and/or agriculturally useful prophylaxes or therapeutics against that
29 agent or toxin;

30 (d) Enhance the virulence of a biological agent or render a
31 nonpathogen virulent;

32 (e) Enhance the ease of transmission of a biological agent from
33 human to human, animal to animal, or animal to human;

34 (f) Enable the evasion of diagnostic/detection modalities;

1 (g) Alter the host range or vector of a biological agent or toxin;
2 (h) Enhance the susceptibility of a host population; or
3 (i) Create a novel biological agent or toxin, reconstitute or
4 revitalize an eradicated, inactive, dormant, or extinct biological
5 agent that is harmful to humans, human habitat, agriculture, or
6 livestock.

7 (2) A principal investigator may seek an exemption to the
8 prohibitions listed in subsection (1) of this section for a specific
9 research project by submitting to the commission, in advance, a written
10 request which specifies in detail the precise research proposed to be
11 carried out, the purpose and need for the exemption, the names of all
12 research sponsors for the research that will be subject to the
13 exemption, the unavailability of alternative means of conducting the
14 research, a clear explanation of any special risks involved in the
15 research or project proposed for exemption, and any extraordinary
16 safeguards and precautions which need to be implemented. The
17 commission may permit exemptions to the prohibitions listed in
18 subsection (1) of this section, only on a research project by project
19 basis; it may not issue a blanket exemption to any particular principal
20 investigator or research sponsor, nor may the commission issue a
21 blanket exemption for a particular type of research project. Any
22 exemption permitted under this section shall be updated and resubmitted
23 to the commission annually for review and reconsideration. Research or
24 projects that are subject to the prohibitions described in subsection
25 (1) of this section shall not be exempted solely on the basis that the
26 research or project has dual purposes or uses, some of which may not
27 violate subsection (1) of this section.

28 (3) Biosafety level 4 laboratories and facilities that contain them
29 are not permitted within Washington state.

30 PART XIII

31 NOTICE POSTING AND DISTRIBUTION OF THIS CHAPTER

32 NEW SECTION. **Sec. 16.** (1) A copy of this chapter shall be
33 distributed to all employees, students, and any other person who has
34 regular access to any portion of a facility or laboratory permitted
35 under this chapter. All entities permitted under this chapter shall
36 have a system for reporting health and safety violations, including a

1 method to report in an anonymous manner to the health and safety
2 officer and a method to report in an anonymous manner to the
3 institutional biosafety committee.

4 (2) A person is not required to conduct scientific research,
5 experimentation, study, or take other action in a laboratory that
6 violates any provision of this chapter or permits issued under this
7 chapter or has reasonable potential to adversely affect public or
8 employee health and safety. A person or employer shall not discharge,
9 refuse to hire, discipline, or in any manner retaliate or take any
10 adverse action against any employee, applicant, or other person because
11 such employee, applicant, or person discloses or threatens to disclose
12 to a supervisor or a governmental agency an activity, policy, or
13 practice that the person reasonably believes is in violation of this
14 chapter; or objects to or refuses to participate in any activity,
15 policy, or practice that the person reasonably believes is in violation
16 of this chapter. In addition to any other remedy provided by law, an
17 employee, researcher, or student aggrieved by a violation of this
18 subsection, within two years, may file a complaint with the attorney
19 general, who, after a proper investigation, may, in proper
20 circumstances, bring an action in the name of the state against the
21 facility alleged to have violated this section. If the attorney
22 general declines to bring an action based on the complaint filed, the
23 attorney general shall expeditiously provide notice of decline to the
24 grievant. The aggrieved employee, researcher, or student may, within
25 one year after said notice, institute a civil action in court of
26 jurisdiction where the facility is located. Any party to said action
27 shall be entitled to trial by jury. Remedies available in common law
28 tort actions shall be available to prevailing parties, in addition to
29 any legal or equitable relief. The court may, in addition to issuing
30 temporary restraining orders or preliminary or permanent injunctions,
31 order the reinstatement of an employee's, researcher's, or student's
32 position, the restatement of salary and fringe benefits and rights,
33 compensation of three times lost wages and benefits or other
34 remuneration, interest for liquidated damages, and/or repayment by the
35 facility of employee's, researcher's, or student's reasonable costs and
36 attorneys' fees.

